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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,367	10/20/2003	Shigeru Nemoto	WAKAB60.001DV1	2857

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EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/689,367

Applicant(s)

NEMOTO, SHIGERU

Examiner

Catherine S. Williams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/780,731.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/26/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

The current status of all nonprovisional parent applications referenced should be included. Specifically, the first sentence of the specification should be amended after "...a divisional of U.S. Patent Application No. 09/708,731, filed February 9, 2001," to include --now Patent No. 6,676,635--. Appropriate correction is required.

Information Disclosure Statement

The information disclosure statement filed 1/26/04 fails in part to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but some of the information referred to therein has not been considered. Specifically, a copy of GB 1,335,290 has not been provided and is not part of the application file. It is asked that a copy be submitted with the next correspondence.

Specification

The disclosure is objected to because of the following informalities:

1. The Summary of the invention is objected to for not being commensurate with the invention as claimed. Generally, the summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously

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existent in the prior art (and preferably indicated in the Background of the Invention).

The present summary seems to be a listing of claims from the parent application which references the invention as a whole and is not directed to the claimed invention.

2. The Brief Description of the Drawings does not reference all the drawings included in the application. Specifically, brief descriptions of figures 3(a)-(d), 4(a)-(c), 5(a)-(d), 6(a)-(b), 15(a)-(c), 16(a)-(b), 38(a)-(c) and 39(a)-(c) are missing.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "blade spring" (claim 3).

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Armbruster et al (USPN 5,322,511). Armbruster discloses an injector that includes a syringe barrel (80) having a flange (92) and a concave portion (94,96,96' or 94,98,98'). See figures 11-12. Figure 10 shows a cylinder holder with a groove (72) for the insertion of the flange. Figure 12 shows the flange inserted in the groove. Figure 16 shows the concave portion (94,98,98') engaging a positioning mechanism (74) of the cylinder holder.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly et al (USPN 4,677,980) in view of Fago et al (USPN 6,569,127).

Reilly discloses a cylinder holder (14') that includes a positioning mechanism (126) being a blade spring (128) with a pawl/latch (126a). See Figure 15. The positioning mechanism (126a) is adapted to engage a concave portion (133) provided on the syringe barrel (18). See 8:34-9:14. The cylinder holder (14') is provided directly on the front of the injection apparatus (10). See figures 1 and 7. The cylinder holder (14') is an adapter (in that it is a separate attachment component) to which the syringe barrel (18) can be mounted when the adapter is set in the injection apparatus. See 14' set in notches (60a and b)) in figure 1. The device also includes insertion pins (124) which are adapted to fix the syringe barrel by holding a flange on the syringe barrel. See Figure 15 and 8:34-9:13.

Reilly meets the claim limitations as described above but fails to include the cylinder holder having an insertion groove.

However, Fago discloses a syringe and injector system that includes a syringe barrel (12) with a flange (16a,16b). The syringe is held by an injector having a cylinder holder (10). See

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figure 1. In this embodiment, the cylinder holder (10) has two grooves (26a,26b) that fix the syringe barrel by holding the flange of the barrel. See figure 1.

At the time of the invention, it would have been obvious to one skilled in the art to substitute the pin/flange attachment of Reilly with the teaching of a groove/flange attachment of Fago. Both devices are analogous in the art of syringe injection systems and both have front-loading syringe barrels; therefore, a combination is proper. Additionally, the pins of Reilly and the grooves of Fago are functional equivalents designed for the same purpose and to solve the same problem, i.e. attachment of the syringe to the front of the injector. Furthermore, one skilled in the art would recognize that the flange/groove attachment of Fago has additional surface area for frictional contact. This added function enhances the design and performance of the flange/groove attachment over the pin/flange attachment by enhancing the mechanical contact of the syringe with the injector and thereby reducing the chance of the syringe from inadvertently becoming dislodged from the injector. The motivation for the incorporation is garnered from the fact that the structures are functional equivalents. Additionally, one skilled in the art would recognize this equivalency. The teaching of a flange/groove attachment would be incorporated to achieve the same function as the pin/flange attachment in addition to enhancing the mechanical stability of the connection.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly in view of Fago in further view of Rait (USPN 5,429,611). Reilly in view of Fago meets the claim limitations as described above including the teaching of a positioning mechanism (126) being a blade spring (128) with a pawl/latch (126a) but fails to teach that the blade spring could be a coil spring.

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However, Rait discloses a syringe with pivotable latches/pawls (20) that are biased by a coiled spring (28). See figures 1 and 3. Rait discloses that the coil spring could be substituted with a leaf spring. See 5:58-62.

At the time of the invention, it would have been obvious to one skilled in the art to substitute the blade spring of Reilly in view of Fago with the teaching of the coil spring by Rait. Blade/leaf and coil springs are well known in the syringe/injector art and are commonly used to bias structural components relative to one another. One skilled in the art would recognize each are used interchangeably and are commonly substituted for one another. See Rait 5:58-62. Additionally, one skilled in the art recognizes that blade/leaf springs are prone to repetitive failure due to their cantilevered structure and can easily fracture at the fulcrum of the spring. Reilly in view of Fago discloses a repetitive use device where the spring would be subject to repetitive failure. Coil springs, albeit can fail, but do not have a single point/ focus of bending and weakness and can better withstand repetitive use than a leaf/blade spring.

Therefore at the time of the invention, it would have been obvious to substitute the blade/leaf spring of Reilly in view of Fago for a coiled spring as taught by Rait in view of common knowledge known by one skilled in the art. The motivation for the substitution would have been in order to provide a spring with enhanced performance for repetitive use.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Catherine S. Williams
February 4, 2005